K001683

AUG 21 2000

510(k) Summary of Safety and Effectiveness Information
Sysmex® R-500, Automated Reticulocyte Analyzer

Sysmex Corporation
Gilmer Road 6699 RFD
Long Grove, IL 60047-9596
Contact Person: Nina Gamperling at 847-379-3675 or by facsimile at 847-726-3559

Trade or Proprietary Name: Sysmex® R-500, Automated Reticulocyte Analyzer

Common or Usual Name: Automated Reticulocyte Analyzer

Classification Name: Automated Reticulocyte Counter

Intended Use: The Sysmex® R-500 is an automated reticulocyte analyzer intended for *in vitro* diagnostic use in clinical laboratories. The following parameters are analyzed: RET%, RET#, and RBC count.

Device Description: The R-500 analyzes reticulocytes using flow cytometry with a semiconductor laser as the light source. The R-500 aspirates whole blood samples without any pretreatment. The analyzer processes approximately 40 samples per hour and provides accurate and precise test results for three analysis parameters in whole blood: Reticulocyte percent, Reticulocyte absolute number, and Red blood cell count. Abnormal marks and error messages indicate sample abnormalities. This is an indication that the sample requires further review and investigation.

Similarities and Differences to Predicate Devices: The Sysmex® R-500 is substantially equivalent in intended use and technological characteristics to previous Sysmex instrumentation. A summary of the comparative features is presented in Table 1.

Supportive Data: Carryover, precision, linearity, and sample stability data show performance to manufacturer specifications. As demonstrated by correlation studies, the performance claims of the proposed device are similar to the predicate devices, R-3500, XE-2100, SE/RAM-1 and R-3000. During those studies, specimens were evaluated from apparently healthy individuals and from patients with different pathological conditions expected to affect the results for particular parameters.

Conclusion: The data presented show that the R-500 is substantially equivalent to previous Sysmex reticulocyte analyzers.

Table 1: Comparative Features of R-500 and Previous Sysmex Instruments

Features (Submission #)	R-500	R-3500 (K981950/S1)	XE-2100 (K992875)	SE-9500/RAM-1 (K964375)	R-3000 (K912494)
FDA Clearance		3-Nov-98	9-Nov-99	13-Mar-97	10-Sep-91
Intended Use	Automated reticulocyte counter for in vitro diagnostic use in clinical laboratories	Automated reticulocyte counter for in vitro diagnostic use in clinical laboratories	Automated hematology and reticulocyte analyzer for in vitro diagnostic use in clinical laboratories	Automated hematology and reticulocyte analyzer for in vitro diagnostic use in clinical laboratories	Automated reticulocyte counter for in vitro diagnostic use in clinical laboratories
Sample Type	Whole blood	Whole blood	Whole blood	Whole blood	Whole blood
Sample Volume	50µL-Manual Mode	250µL- Cap piercer 125µL –Manual Mode 40µL-Capillary dilution	200µL- Cap piercer 130µL –Manual Mode 40µL-Capillary dilution	250µL- Cap piercer 125µL –Manual Mode 40µL-Capillary dilution	100µL- Sampler 100µL- Manual Mode
Performance	Similar to other instruments listed	Proven performance	Proven performance	Proven performance	Proven performance
Reticulocyte Parameters	RBC, RET%, RET#	RBC, RET%, RET#, IRF, HFR, MFR, LFR	RBC, RET%, RET#, IRF, HFR*, MFR*, LFR* *Not reportable in USA	RBC, RET%, RET#, IRF	RBC, RET%, RET#
Reticulocyte Reagents	RETSHEATH RETSEARCH II CELLPACK	RETSHEATH RETSEARCH CELLPACK	RETSHEATH RETSEARCH II CELLPACK	RETSHEATH RETSEARCH CELLPACK	RETSHEATH, RETSEARCH
Reticulocyte Principles	Flow Cytometry Sheath flow	Flow Cytometry Sheath flow	Flow Cytometry Sheath flow	Flow Cytometry Sheath flow	Flow Cytometry Sheath flow
Dimensions (HxWxD) (mm)	Main unit: 600x480x500 (Pneumatic unit: 333x195x395)	Main unit: 720x630x505 (Pneumatic unit: 33x195x395)	Main unit: 711x706x912 (Pneumatic unit: 333x195x395)	Main unit: 720x636x820 (Pneumatic unit: 333x195x395)	Main unit: 645x600x618 (Pneumatic unit: 390x340x500)
Weight (kg)	Main Unit: 50 (Pneumatic unit: 15.5)	Main unit: 85.5 (Pneumatic unit: 15.5)	Main unit: 93 (Pneumatic unit: 15.5)	Main unit: 80 (Pneumatic unit: 15.5)	Main unit: 66 (Pneumatic unit: 31)
Bar Code	No	Yes	Yes	Yes	Yes
No. of Tests / Hr	Approximately 40	Approximately 120	Approx 113 (CBC + RET)	Approximately 80	Approximately 80

DEPARTMENT OF HEALTH & HUMAN SERVICES

AUG 21 2000

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Nina M. Gamperling, MBA, MT (ASCP), RAC
Manager, Regulatory Affairs
Sysmex Corporation of America
Gilmer Road, 6699 RFD
Long Grove, Illinois 60047-9596

Re: K001683
Trade Name: Sysmex® R-500, Automated Reticulocyte Analyzer
Regulatory Class: II
Product Code: GKL
Dated: May 31, 2000
Received: June 1, 2000

Dear Ms. Gamperling:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K001683

Device Name: Sysmex® R-500, Automated Reticulocyte Analyzer

Indications For Use:

The Sysmex® R-500 is an automated reticulocyte analyzer intended for *in vitro* diagnostic use in clinical laboratories. The following parameters are analyzed:

RET%	Reticulocyte percent
RET#	Reticulocyte absolute count
RBC	Red blood cell count

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CHRD, Office of Device Evaluation (ODE)

Peter E Maxim

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001683

Prescription Use ✓ **OR** **Over-the-Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)